REMARKS

Status of Claims

Claims 1-6, 8-17, 20, 26, 28-31, 38, 40, 42 and 59-97 are pending. Claims 8-9, 17-20, 26, 28-31, 38, 40, 42 and 81-95 have been withdrawn from consideration in response to a restriction requirement. Claims 7, 19, 24, 25, 27, 32-37, 39, 41, and 44-58 were previously canceled, and claim 11 is canceled herein. In this amendment, claims 96 and 97 (mirroring claims 1 and 11, respectively), have been added. No new matter has been added as a result of the addition of these claims.

Claim Amendments

Claims 1, 6 and 63-70 have been amended to correct obvious typographical errors such as would be readily apparent to one skilled in the art. In particular, claims 6 and 63-70 have been amended to recite an amino acid substitution "within the sequence comprising amino acids 133 to 145 of HBsAg." Support for these amendment can be found on page 28, lines 21-26 of the specification, and in the originally filed claims. In claims 4 and 60-62, Applicants have deleted the phrase "or in the region of the 'a' determinant", not due to any perceived or apparent claim defect, but merely to more specifically set forth the subject matter of the applicants' invention. Claim 10 has been amended to correct a typographical error. Specifically, the term "NS" HBsAg has been amended to recite "NP" HBsAg. Applicants thank the Examiner for catching this typographical error. Claim 11 has been cancelled, and newly added claim 97 (which corresponds to claim 11) omits any reference to a point mutation at a codon which comprises amino acid 145.

Rejection of Claims 1, 4, 6, 11, and 60-70 under 35 U.S.C. §112, Second Paragraph

The Examiner rejects claims 1, 4, 6, 11, and 60-70 under 35 U.S.C. §112, second paragraph, as failing to particularly point out and distinctly claim the

subject matter which applicant regards as the invention. According to the Examiner, the term "is capable of binding" in claims 1 and 11: (1) is not defined by the claim; (2) the specification does not provide a standard for ascertaining the requisite degree; and (3) one of ordinary skill in the art would not be reasonably appraised of the metes and bounds of the invention (See, Office Action mailed December 8, 2005, page 3). Applicants respectfully traverse this rejection for at least the following reasons.

Applicants respectfully draw the Examiner's attention to the fact that the claims are drawn to antibodies which are not merely "capable of binding", but are instead "capable of binding specifically" to certain antigens (namely, wildtype HBsAg and at least two mutant forms of HBsAg). Antibodies which are capable of binding specifically to the recited antigens are covered by the claims. In contrast, those antibodies which are not capable of binding specifically to the recited antigens are not covered by the claims. Therefore, the word "specifically" provides a sufficient means for determining the metes and bounds of the claims. As discussed in the specification on page 5, lines 13-15 "[A] skilled worker is able readily to distinguish specific binding between an antibody and an antigen from non-specific binding."

Applicants submit that the phrase "capable of binding specifically" is not indefinite and that the meaning of this phrase is well-known to those skilled in the art. More particularly, it is well-known to those skilled in the art that while an antibody may specifically bind to a specific antigen that said specific binding (between said antibody and antigen) may not occur 100% of the time. For example, an antibody may, while capable of specifically binding to an antigen, not actually specifically binding to said antigen because the antibody is in competition with another antibody for binding to said antigen. Applicants further submit that because this phrase would be readily understood by those skilled in the art that the specification does not need to define this phrase. As the Federal Circuit stated in *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367

(Fed. Cir. 1986), "[A] patent need not teach, and preferably omits, what is well known in the art." Therefore, the rejection of claims 1 and 11 under 35 U.S.C. §112, second paragraph is improper and should be withdrawn. Moreover this rejection should not be applied to newly added claims 96 and 97, which mirror claims 1 and 11, respectively.

With respect to claims 6 and 63-70, Applicants have amended these claims to recite an amino acid substitution "within the region comprising amino acids 133 to 145 of HBsAg." Thereupon, in view of this amendment merely correcting an inadvertent grammatical error which would be readily apparent to one skilled in the art, Applicants submit that the rejection of claims 6 and 63-70 under 35 U.S.C. §112, second paragraph is now moot and should be withdrawn.

With respect to claims 4 and 60-62, Applicants have amended these claims to delete the reference to the "region of the 'a' determinant". Thereupon, in view of this amendment, Applicants submit that the rejection of claims 4 and 60-62 under 35 U.S.C. §112, second paragraph is now moot and should be withdrawn.

Rejection of Claims 1-6, 10, 12-16, 59-80 Under 35 U.S.C. §112, First Paragraph

The Examiner rejects claims 13, 14, and 15 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. According to the Examiner, there is no indication in the specification as to public availability of the hybridoma cells producing the claimed monoclonal antibodies (See, Office Action mailed December 8, 2005, page 4.)

As suggested by the Examiner, the undersigned attorney hereby states that the deposits were made under the Budapest Treaty and that the specific strains of hybridoma cells as recited in claims 13, 14, and 15 will be irrevocably

and without restriction or condition released to the public upon the issuance of a U.S. patent.

The Examiner rejects claims 1-6, 10, 12, 16, and 59-80 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. According to the Examiner, the aforementioned claims are directed to a genus of monoclonal antibodies that are capable of binding to amino acids 133-145 of any known and unknown HBsAg (See, Office Action mailed December 8, 2005, page 7). The Examiner further states that Applicants have "not disclosed sufficient species for a genus of monoclonal antibodies that are capable of binding two of any known and unknown HBV as broadly claimed." *Id.* The Examiner concludes that "there is no indication that Applicant was in possession of a monoclonal antibody of IgM to HBsAg, nor a monoclonal antibody in a humanized form, nor all monoclonal antibodies to has (sic) an amino acid substitution within amino acids 133 to 145 of HBsAg, nor a genus of monoclonal antibodies that is capable of binding specifically to wild-type HBsAg and to any two known or unknown HBsAg variants as broadly claimed." Applicants respectfully traverse this rejection.

Applicants have discovered a monoclonal antibody that is capable of binding specifically to both the wildtype and to at least two mutant forms of HBsAg. The Federal Circuit held that "as long as an applicant has disclosed 'a fully characterized antigen', either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen." *Noelle v. Lederman*, 355 F.3d 1343, at 1349 (Fed. Cir. 2004) (hereinafter "*Noelle*").

Applicants have fully complied with the Federal Circuit's requirements as articulated in *Noelle*. The specification describes HBsAg, the surface antigen on the outer coat of the hepatitis B virus (hereinafter "HBV"). Moreover, as also discussed in the specification, "HBsAg contains the major neutralizing epitope of HBV, termed the 'a' determinant, which spans amino acids 124 to 147 and is common to all HBV isolates" (See, specification, page 1, lines 29-31). The specification further teaches that the "a" determinant may involve a disulphide bridge between amino acids 124 and 137, and a second disulphide bridge between amino acids 139 and 147 (See, specification, paragraph bridging pages 1 and 2). The specification also describes that the claimed monoclonal antibody has the capability of binding to both the wildtype and to at least two mutant forms of HBsAg, thus suggesting the antibody is binding to a region of the surface antigen that is conserved between the wildtype and the mutant forms. Additionally, the specification describes the isolation and characterization of several specific monoclonal antibodies that are capable of binding to the wildtype and to at least two mutant forms of HBsAg, namely, the monoclonal antibodies produced by the P2D3, M3A10, and M4F5 clones. Even if the Applicants had not provided all functional definitions of the antibody, this is not necessary per current law. As the Federal Circuit stated in *Noelle*:

> For example, the PTO would find compliance with 112, paragraph 1, for a claim to an isolated antibody capable of binding to antigen X, notwithstanding the functional definition of the antibody, in light of the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature. *Noelle v. Lederman*, 355 F.3d 1343, at 1349 (Fed. Cir. 2004) (quoting *Enzo Biochem v. Gen-Probe, Inc.*, 3232 F.3d 956, 970 (Fed. Cir. 2002)).

Applicants have disclosed a fully characterized antigen (namely, HBsAg) and several antibodies which bind to this antigen, thus satisfying the Federal Circuit's test as articulated in *Noelle*. Therefore, Applicants submit that the rejection of claims 1-6, 10, 12, 16, and 59-80 under 35 U.S.C. Section 112, first paragraph is improper and should be withdrawn.

Rejection of Claim 11 Under 35 U.S.C. §102 (b)

The Examiner rejects claim 11 as being anticipated by Waters (WO 94/21812). Applicants respectfully traverse this rejection.

Claim 11 has been cancelled. Newly added claim 97 corresponds to claim 11 but does not encompass the point mutation at the codon which encodes amino acid 145. Therefore, in view of this amendment, this rejection is now moot and should be withdrawn.

CONCLUSION

Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. Sections 102 and 112. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below. If the Examiner notes any matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge Deposit Account No. 23-0785.

Respectfully submitted,
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